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18. 510(K) SUMMARY

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765 Phone: 800-729-9010 x8534 Fax: 909-839-8804
Contact Person:	John Jimenez Senior Specialist, Regulatory Affairs
Date:	October 31, 2011
Trade or Proprietary Name:	LASSO® 2515 NAV *eco* Variable Catheter LASSO® NAV *eco* Catheter
Common or Usual Name of Device:	Electrophysiological Mapping Catheter
Classification Name:	Electrode Recording Catheter (21 CFR 870.1220, Product Code DRF)
Predicate Devices:	LASSO® 2515 NAV Variable Catheter 510(k): K081258 LASSO® NAV Catheter 510(k): K093376
Manufacturer:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
Manufacturing Sites:	Biosense Webster, Inc. 15715 Arrow Highway Irwindale, CA 91706 Biosense Webster, Inc. Cordis de Mexico Circuito Interior Norte #1820 Parque Industrial Salvarcar 32599 Juarez, Chihuahua, Mexico

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18.1 Substantially Equivalent To

The Biosense Webster LASSO®2515 NAV *eco* Variable Catheter is substantially equivalent to the Biosense Webster LASSO®2515 NAV Variable Catheter [510(k) K081258, cleared January 6, 2009] and the Biosense Webster LASSO® NAV Catheter (510(k) K093376, cleared June 18, 2010).

18.2 Description of the Device Subject to Premarket Notification

The LASSO 2515 NAV *eco* Variable Catheter and the LASSO NAV *eco* Catheter have been designed to facilitate electrophysiological mapping of the atria of the heart with the CARTO 3 EP Navigation System and a reference device. Both catheters are deployed in the right or left atrium through an 8F guiding sheath. Both deflectable catheters consists of a circular spine on the distal tip, with platinum/iridium electrodes that can be used for stimulation and recording. The purpose of this Premarket Notification is to modify the catheter connector, so that the Printed Circuit Board (PCB) can be removed from the single-use only catheter and placed in a reusable interface cable as part of the CARTO 3 EP Navigation System.

The LASSO 2515 NAV *eco* Variable Catheter features a Nitinol loop design that allows the expansion and contraction of the loop to custom-fit veins with different sizes, ranging from 25mm to 15mm diameter (± 15%).

The LASSO NAV *eco* Catheter is a fixed catheter with three fixed catheter sizes, namely 15, 20, and 25 mm loop sizes to accommodate different vein sizes. Each loop size will be available with either 10 or 20 electrodes.

The proposed catheters will continue to interface with standard recording equipment via interface cables and appropriate connectors.

18.3 Indications for Use

LASSO® 2515 NAV *eco* Variable Catheter
The LASSO® 2515 NAV *eco* Variable Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® 2515 NAV *eco* Variable Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 2.3.)

LASSO® NAV *eco* Catheter

The LASSO® NAV *eco* Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® NAV *eco* Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 2.3.)

18.4 Performance Data

The LASSO 2515 NAV *eco* Variable Catheter and the LASSO NAV *eco* Catheter underwent Bench and Animal Testing. Both catheters passed all intended criteria in accordance with appropriate standards and test criteria.

18.5 Overall Performance Conclusions

The nonclinical studies demonstrate that the LASSO 2515 NAV *eco* Variable Catheter and the LASSO NAV *eco* Catheter are safe and effective for anatomic mapping of the heart and establish equivalence of the LASSO 2515 NAV *eco* Variable Catheter and the LASSO NAV *eco* Catheter to their respective predicate devices, the LASSO 2515 NAV Variable Catheter and the LASSO NAV Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 5 2011

Biosense Webster, Inc.
c/o Mr. John Jimenez
Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K113213
Trade/Device Name: LASSO® 2515 V eco Variable Catheter and LASSO® NAV Catheter
Regulatory Number: 21 CFR 870.1220
Regulation Name: Catheter, Electrode Recording
Regulatory Class: II (two)
Product Code: 74 DRF
Dated: October 31, 2011
Received: November 1, 2011

Dear Mr. Jimenez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113213

7. INDICATIONS FOR USE STATEMENT

510(k) No (if known): _____

Device Name: LASSO® 2515 NAV *eco* Variable Catheter and LASSO® NAV *eco* Catheter

Indication for Use:

LASSO® 2515 NAV *eco* Variable Catheter
The LASSO® 2515 NAV *eco* Variable Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

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LASSO® NAV *eco* Catheter
The LASSO® NAV *eco* Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® NAV *eco* Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 2.3.)

Prescription Use (Part 21 CFR 801 Subpart D) ___√___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113213